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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SODERQUIST, ARLEN

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 07/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/763,419

Applicant(s)

MALIK ET AL.

Examiner

Arlen Soderquist

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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1. Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the claims contains an improper Markush group since the group is not closed. Applicant should use the following language when forming a Markush group – “selected from the group consisting of”. Regarding claim 4, the phrase “such as” renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). It is not clear what the scope of the claim is for these claims because a broad limitation, polyalkylene glycol, is followed by a narrow limitation, Ucon. Claim 4 also uses trademarks/tradenames to identify materials. The trademark/tradename refers to the producer of the material, is not a definite identifier of the material.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11 are rejected under 35 U.S.C. 102(a,b) as being clearly anticipated by Wang or Hayes.

The Wang paper has an authorship that is different from the instant inventorship. In the paper Wang teaches sol-gel column technology for single-step deactivation, coating, and stationary-phase immobilization in high-resolution capillary gas chromatography. A sol-gel chemistry-based novel approach to column technology for high-resolution capillary gas chromatography is described that effectively combines surface treatment, deactivation, coating, and stationary phase immobilization into a single step. In the conventional approach, these operations are carried out in separate steps that make column fabrication a time-consuming job. In the taught approach, a cleaned fused silica capillary is filled with a sol solution of appropriate composition, and sol-gel reactions are allowed to go on inside the capillary for a controlled period, typically 15-60 min. A wall-bonded coating results due to condensation of the surface silanol groups with the sol-gel network evolving in their vicinity. Because of the direct chemical bonding to fused silica substrates, sol-gel coatings possess significantly higher thermal stability than conventional

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coatings. This is especially important for thick and/or polar stationary phase coatings that are difficult to immobilize. Scanning electron microscopic studies revealed that sol-gel coatings were characterized by roughened surfaces, providing a number of chromatographic advantages, including higher surface area and faster mass transfer kinetics. Sol-gel column technology does not require any free radical crosslinking procedures for stationary phase immobilization and easily avoids any undesirable changes in the stationary phase properties that might be associated with the crosslinking reactions used in conventional technology. Sol-gel-coated poly(dimethylsiloxane) and Ucon columns provided efficient separations for analytes from a wide polarity range, including free fatty acids, phenolic compounds, amines, aldehydes, ketones, alcohols, and diols that are prone to peak tailing due to adsorptive interactions with the column walls. This suggests excellent quality of column deactivation. The technology provided at least a 10-fold reduction in column preparation time. The sol-gel approach is universal in nature and can be effectively applied to a wide range of microcolumn separation techniques. The experimental section of Wang is identical or equivalent to page 20, line 1 to page 26, line, 2 of the instant specification. Also figures 1-2 of Wang are identical to figures 4-5 of the instant specification.

The Hayes reference teaches sol-gel chemistry-based Ucon-coated columns for capillary electrophoresis. A sol-gel chemistry-based novel approach for the preparation of a Ucon-coated fused-silica capillary column in capillary electrophoresis is presented. In this approach the sol-gel process is carried out inside 25 μ m I.D. fused-silica capillaries. The sol solution contained appropriate quantities of an alkoxide-based sol-gel precursor, a polymeric coating material (Ucon), a crosslinking reagent, a surface derivatizing reagent, controlled amounts of water and a catalyst dissolved in a suitable solvent system. The coating procedure involves filling a capillary with the sol solution and allowing the sol-gel process to proceed for an optimum period.

Hydrolysis of the alkoxide precursor and polycondensation of the hydrolyzed products with the surface silanol groups and the hydroxy-terminated Ucon molecules lead to the formation of a surface-bonded sol-gel coating on the inner walls of the capillary. The thickness of the coated film can be controlled by varying the reaction time, coating solution composition and experimental conditions. Commercial availability of high purity sol-gel precursors (e.g., TEOS 99.999%), the ease of coating, run-to-run and column-to-column reproducibility, and long

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column lifetimes make sol-gel coating chemistry very much suitable for being applied in analytical microseparations column technology. Test samples of basic proteins and nucleotides were used to evaluate the column performance. These results show that the sol-gel coating scheme has allowed for the generation of biocompatible surfaces characterized by high separation efficiencies in CE. For different types of solutes, the sol-gel coated Ucon column consistently provided migration time R.S.D. values of the order of 0.5%. The experimental section of Hayes is identical or equivalent to page 22, lines 8-24 of the instant specification. Also figure 1 of Hayes is identical to figure 3 of the instant specification.

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional prior art relates to sol-gels and their use in chromatography column preparation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (703) 308-3989. The examiner's schedule is variable between the hours of about 5:30 AM to about 5:00 PM on Monday through Thursday and alternate Fridays.

For communication by fax to the organization where this application or proceeding is assigned, (703) 305-7719 may be used for official, unofficial or draft papers. When using this number a call to alert the examiner would be appreciated. Numbers for faxing official papers are 703-872-9310 (before finals), 703-872-9311 (after-final), 703-305-7718, 703-305-5408 and 703-305-5433. The above fax numbers will generally allow the papers to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



June 30, 2003

ARLEN SODERQUIST
PRIMARY EXAMINER